CATHETER

Cross Reference to Related Applications

The present application is a continuation in part of provisional patent application 60/018,333 filed 05/24/96 entitled "Thrombectomy Catheter". This provisional application is incorporated herein in its entirety and the benefit of its filing date is claimed for all that it teaches.

1. Field of the Invention

The invention relates generally to a catheter, and more particularly to a device that utilizes the energy in a pressurized fluid to interact with and remove occlusive material from vessels or lumens in the body.

2. Background of the Invention

Catheters which are used to remove occlusive material from lumens within the body are well known. Occlusive material such as plaque, atheroma, and emboli vary in their mechanical properties and various energy sources have been proposed to break up occlusive material. These proposals include the use of high energy fluid jets or the circulation of an abrasive slurry within the vessel. The use of mechanical impellers and/or blades has been proposed and experimental work has been performed with a "rotoblader" device. Laser light energy and either ultrasonic or acoustic energy have been proposed to breakdown occlusive material. The use of radio frequency electromagnetic energy has been proposed as well.

For example fluid pressure thrombectomy systems are known from United States Patent No. 4,690,672 to Veltrup among others. In the Veltrup device, a reward-facing jet entrains thrombus and blood from the patient, and ejects these into a secondary discharge lumen which removes both thrombus and blood from the body. Linear or straight line fluid jets which

represent the current technology, are relatively inefficient in removing thrombus because of the jet geometry.

Impeller based cutting devices are known from United States Patent No. 4,729,763 among others. In this device the mechanically rotated blade interacts directly with the occlusive material.

Ultrasonic based devices are known from United States Patent No. 5,368,557. In this device the ultrasonic energy is used to break up the occlusive material and a fluid is supplied to cool the ultrasonic tip. In general there are two functions which must be supplied. First sufficient energy must be available to disrupt the occlusive material. Secondly loose material must be efficiently removed from the body. Most particulate occlusive material is thrombogenic and failure to remove this material can result in a distal embolism.

SUMMARY OF THE INVENTION

In contrast to the devices of the prior art, the present invention teaches the use of a deflected jet alone or in conjunction with a complimentary energy source to break up and transport occlusive material out of the body. The deflected jet is a substantially annular sheet of fluid which becomes attached to a barrier and which is then deflected through an angle. This deflected jet entrains ambient fluid on its outer surface and the combined stream is deflected through an angle of about ninety degrees in most embodiments. This deflected jet presents a large and energetic surface to entrain and emulsify occlusive material. In operation the jet emerges from a generally annular nozzle or slit and attaches itself to a shoulder of a flow control body. As the jet emerges from the nozzle it

spreads over the contour of the shoulder which gives the jet a greater working area. The jet ultimately enters a throat formed in the catheter which provides good pressure recovery for the jet improving overall efficiency.

In some versions, the catheter may be delivered over a guide wire or through a guide sheath. The construction and geometry of the device permits integration with other energy sources. In these alternate embodiments the deflected jet acts a pump to emulsify and preferentially remove particulate occlusive material. Examples of disclosed energy sources include mechanical impellers, ultrasonic probes, radio frequency probes, and laser fiber systems.

BRIEF DESCRIPTION OF THE DRAWING

The drawings show illustrative embodiments of the catheter. Various modifications to these designs may be made without departing from the scope of the invention. Elements which carry identical reference numerals are equivalent structures.

Fig. 1 is a system level diagram, showing a simple version of the catheter system;

Fig. 2 is a schematic diagram of the distal end of the catheter;

Fig. 3 is a schematic diagram of an alternate embodiment of the catheter;

Fig. 4 is a schematic diagram of an alternate embodiment of the catheter.

Detailed Description

Turning to Fig. 1, the catheter assembly 10 is coupled to an angiographic fluid injector 12. The catheter assembly 10 has a distal end 11 and a proximal end 13. The proximal end includes fittings for a high pressure supply lumen 18 and a lower pressure discharge lumen 20 and a guide wire lumen 22. In the figure the high pressure injector 12 supplies saline from a saline supply at a user selected delivery rate which generates a corresponding pressure sufficient to induce the required flow. Typically, an over-pressure switch is present on the injector 12 to shut the injector off if the high pressure supply line pressure exceeds a pre-set value. In use, the distal end 11 of the catheter assembly 10 interacts with the thrombus or other occlusive material and the energetic saline fluid jet entrains both blood and thrombus from the patient, which are discharged through the lower pressure discharge lumen 20 to a collection vessel 22. In the preferred use, the catheter 10 is delivered by the guide wire 26 to an occluded site in the vasculature. The injector 12 is then activated and the occlusive material is extracted by the deflected jet into the collection vessel 22.

Fig. 2, shows the distal 11 end portion of an illustrative embodiment of the catheter assembly 10 in cross section. The outer diameter of the catheter assembly 10 is defined by the sheath 24. The interior lumen of this sheath 24 forms and defines one wall 35 of a throat 36 formed between the wall 35 and the outer diameter of the flow control body 16. The sheath 24 also defines a central axis 37 for the distal portion 11 of the assembly. The high pressure supply tubing 19 has a lumen 18 which is used to deliver fluid to a slit 40. The slit 40 discharges fluid in a generally radial direction with respect to the central axis 37. In operation, the slit 40

will have dimensions defining an orifice area smaller than the cross-sectional dimension of the interior of the high pressure supply lumen 18. In the figure the slit 40 directs the jet away from the central axis at ninety degrees but other angles are contemplated within the scope of the disclosure. A small land area 42 may be formed on the flow control body 16. This land area ~~24~~ 42 helps to turn the sheet of fluid 44 which emerges from the slit 40. As the fluid emerges, it entrains fluid on both sides of the jet. Since the amount of fluid which can be entrained on the inner side next to the flow control body 16 is limited, the jet turns and follows the contour of the body 16, thus turning through approximately ninety degrees in the illustrative example into the annular throat 36 formed between the sheath 24 and the body 16. Both lesser and greater degrees of turning are contemplated at least between 45 and 270 degrees. Ninety degrees of turning is desirable because it presents more fluid entrainment area to engage and eject thrombus. The non-symmetrical jet is highly turbulent and has many eddies. As a consequence the average velocity in the outer surface of the jet is higher than the average flow over the attachment wall 17 of the flow control body 16. Therefore the jet velocity is higher than a conventional jet at the same distance.

This embodiment of the device also shows a guide wire 26 which may be used to position the sheath 24 within a body vessel. For use in coronary applications, it is important that the guide wire be small, and the sheath 24 is shown with an opening 46 which permits the sheath 24 to be delivered over the guide wire 26. It should also be noted, that the position of the aperture 46 is sufficiently proximal of the distal end of the sheath 24 to permit retraction of the guide wire 26 fully into the discharge lumen ~~20~~.

As seen in the figure there is a strut 41 which anchors the cap 19 into the flow control body 16. This strut 41 may extend beyond the cap 19 toward the open distal end of the sheath 24. If appropriately formed this portion of the strut may serve as a fixed guide wire and extend as shown by dotted line 87 in the figure. Thus the flow body 16 may have a guide wire element or the sheath 24 may be advanced over a guide wire 26. As seen in the figure the strut can extend toward the proximal end of the catheter and serve as a fixed guide wire 87.

In the embodiment shown in Fig. 2 it is possible to move the flow control body 16 with respect to the sheath. When a small (3F) flow body is used, the sheath and flow body 16 may be advanced sequentially. The high pressure tubing 19 may be made of hypo tubing or more preferably polyimide tubing. When metal hypo tubing is used the flow body and tubing have the mechanical properties of a guide wire and may be used instead of a guide wire to position the flow body. If polyimide tubing is used the injector can be used to provide low pressure fluid to stiffen the tubing 19 permitting it to be used as a guide wire as well. It should also be noted that the cap 19 may be positioned off center to provide a flow body which advances and turns as it is activated outside the sheath 24. When viewed under imaging equipment this version of the device is steerable under physician control.

Fig. 3 shows an illustrative alternate second embodiment or design for the catheter assembly 10. In this version of the device an additional energy source is provided. For example an air motor 50 is coupled by a flexible shaft 52 to a distal impeller 54. In operation the impeller is rotated inducting thrombus or other occlusive material into the sheath 24.

The masticated material accumulates near the flow control body 16 and the deflected jet 60 entrains this material and ejects it from the device as indicated by stream 62. In this fashion a mechanical blade or impeller can supplement the action of the deflected jet to treat patients with more organized occlusive material.

Fig. 4 shows a remote energy source 70. Several different sources are represented generically by block 70. Specifically included are sources for laser light energy, ultrasonic acoustic energy, and radio frequency electromagnetic energy. In the case of ultrasonic energy and radio frequency energy the probe section may be metal. If the energy source is laser light the probe 72 may be an optical fiber with a lens or other distribution optic at the distal tip of the probe 72. In general the probe which extends distal of the flow control body 16 is connected to the energy source 70 through a suitable conduit 74.